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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/813,421
Filing Date: March 30, 2004
Appellant(s): HARTER ET AL.

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Robert J. Harter
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 02/11/2008 appealing from the Office action

mailed 05/04/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

A substantially correct copy of appealed claims 1, 3-33 appears on page 35-40 of the Appendix to the appellant's brief. The minor errors are as follows:

- The listing of claim 8 on page 36 line 2 includes markings that should have been removed to form a clean claim listing.

(8) Evidence Relied Upon

Berkow, Robert "The Merck Manual of Diagnosis and Therapy" Merck Research Laboratories, Sixteenth Edition (1992), pp 88-90, 328-331, 335-336, 650

Evans, R. Scott "A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents" The New England Journal of Medicine, vol338, no. 4 (Jan 22, 1998), pp. 232-238

4,752,889	RAPPAPORT	6-1988
6,401,057	KADTKE	6-2002
5,910,421	SMALL	6-1999
5,486,999	MEBANE	1-1996
2002/0013538	TELLER	1-2002

Lowy, Franklin D. "Staphylococcus aureus Infections" The New England Journal of Medicine, vol339, no. 8 (Aug 20, 1998), pp. 520-532

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1.   Determining the scope and contents of the prior art.
2.   Ascertaining the differences between the prior art and the claims at issue.
3.   Resolving the level of ordinary skill in the pertinent art.
4.   Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-4, 7, 12, and 14-29 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Berkow in view of Evans.

As per claim 1, Berkow teaches a method capable of identifying a specific food

allergen (reads on "a suspect influencing agent") capable of causing an allergic reaction

in a patient (page 328-330), wherein the specific food is selected from a plurality of

commonly incriminated food allergens (reads on "a plurality of possible influencing

agents") (page 329 paragraph 7) comprising:

(a) identifying possible allergens (page 329 paragraph 6, page 330 Table 20-2);

(b) identifying the reaction (page 329 paragraph 6);

(c) identifying possible allergens the patient was exposed to during a first,

second, and third period during which period the patient was exposed to a first, second,

and third diet, respectively (page 329 paragraph 6, page 330 Table 20-2);

(d) identifying symptoms during any period (page 329 paragraph 8);

(e) determining the relationship between food and symptom in the patient (page

329 paragraph 6).

According to the teachings of Berkow, the method diagnoses a plurality of

allergic reactions by attempting to correlate a symptom exhibited by the patient to a

plurality of possible allergens, e.g. foods, environmental exposure (page 650 paragraph

4), etc.

Additionally, Berkow also teaches that the patient may be monitored for at least

three weeks, each week on a different diet. This is evident because Diet 4 is intended

to be applied when the first three diets have been exhausted with no improvement.

Berkow also teaches that patterns of symptoms may be correlated to environmental

exposure, including food, to diagnose an allergic reaction.

Berkow does not teach the use of a "computer" and "a computer display" to

automate the selection of allergens and reaction.

Evans teaches "a computerized decision-support program linked to computer-

based patient records that can assist physicians in the use of antiinfective agents and

improve the quality of care" (page 232 column 1 paragraph 1, page 234 column 1

paragraph 2, Table 1). Evans further teaches that "[w]hen physicians select their own treatment plans, the computer automatically checks for allergies" (page 234 column 1 paragraph 3).

According to the teachings of Evans, the program is capable of linking patient record to assist therapeutic decisions, as well as enabling the physician to select and display data.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Evans in the embodiment of Berkow with the motivation of facilitating physician diagnosis by providing patient data at the point-of-care (Evans; page 236 column 2 paragraph 1).

As per claim 3, Berkow teaches determining the relationship between food and symptom in the patient by exposing the patient to a challenge and observing the patient's response thereto (page 329 paragraph 6). Berkow further teaches confirming positive challenges (reads on "sorting") (page 329 paragraph 6).

Evans also teaches that the program is capable of sorting data (page 233 Figure 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Evans within the embodiment of Berkow and Evans, with the motivation of displaying data in an orderly manner as to quickly apprise the physician of the relevant information (Evans; page 233 Figure 1).

As per claim 4, Berkow teaches the addition of new possible allergens and monitoring for changes in symptoms (page 329 paragraph 8) (It is noted that new foods are considered "an additional possible influencing agent").

As per claim 7, Berkow teaches monitoring the recrudescence of symptoms (page 329 paragraph 8).

As per claim 12, Berkow teaches that the clinical significance of a positive skin test "is determined when results are correlated with the pattern of symptoms and related to environmental exposures" (page 650 paragraph 4) (It is noted that the correlation represents the clinical significance of a positive skin test. Therefore, the correlation represents the likelihood that the agent in question is the allergen, and, as such, the likelihood that the agent may cause future reactions).

Berkow also teaches food abstinence to prevent future allergic reactions (page 329 paragraph 9) (It is noted that once the influencing agent, i.e. food, is identified, the patient should abstain from consuming such food in the future because it is likely that the food will cause a reaction when ingested).

As per claim 14, Berkow teaches that the influencing agent may be foodstuff (pages 328-330).

As per claim 15, Berkow teaches that individual ingredients in foods may cause reactions (page 329 paragraph 7).

As per claim 16, Berkow teaches that the symptom occurs some time after the food is ingested (page 329 paragraph 6 and 8).

As per claim 17, Berkow teaches establishing clinical significance for a positive skin prick test (page 650 paragraph 4).

Notwithstanding the above, Evans teaches using a 95 percent confidence interval (page 235 column 1 paragraph 1).

At the time the invention was made, it would have been obvious to include the teachings of Evans within the embodiment of Berkow and Evans with the motivation of accurately determining the reliability of the calculated data when performing a study to determine the possible allergen (Evans; page 235 column 1 paragraph 1).

As per claim 18, Berkow teaches that each period may be one day or more (page 329 paragraph 8, page 330 Table 20-2) (It is noted that Berkow intends for each elimination phase to last between a day and a week if the patient's symptoms are relieved; the patient's diet may also be changed daily, signifying the start of a new period of monitoring for symptoms).

As per claim 19, Berkow teaches that "[c]ommonly incriminated food **allergens** include milk, eggs, shellfish..." (page 329 paragraph 7).

As per claim 20, Berkow teaches determining the relationship between food and symptom in the patient by exposing the patient to a challenge and observing the patient's response thereto (page 329 paragraph 6). Berkow further teaches confirming positive challenges (reads on "sorting") (page 329 paragraph 6). Berkow further teaches that the clinical significance is determined when skin test results are correlated with the pattern of symptoms and related to environmental exposures (page 650 paragraph 4).

As per claim 21, Berkow teaches that "[e]osinophilic enteropthy, which may be related to specific food allergy, is an unusual illness with **pain**..." (page 328 paragraph 5) (It is noted that this symptom is a reaction with pain).

As per claim 22, Berkow teaches that "[f]ood additives can produce... asthma" (page 329, paragraph 3) (It is noted that asthma is considered "respiratory-related").

As per claim 23, Berkow teaches that "perianal eczema have been attributed to food allergy" (page 328, paragraph 5) (It is noted that perianal eczema is considered to be "skin-related").

As per claim 24, Berkow teaches that "[e]osinophilic enteropthy, which may be related to specific food allergy, is an unusual illness with pain... that is associated with blood eosinophilia" (page 328, paragraph 5) (It is noted that blood eosinophilia is considered to be related to "blood pressure").

As per claim 25, Berkow teaches that the reaction is suboptimal athletic performance (page 328 paragraph 5) (It is noted that suboptimal athletic performance is considered to be "fatigue").

As per claims 26 and 28, Berkow teaches that the reaction is depression (page 328 paragraph 5) (It is noted that depression is considered to be "mentally-related").

As per claim 27, Berkow teaches that allergy could bring on anaphylaxis, a potentially fatal acute attack (page 330 paragraph 10). Berkow also teaches that patients who experience anaphylaxis may convulse and die (page 331 paragraph 3) (It is noted that convulsions are considered a form of "seizure").

As per claim 29, Berkow teaches that smoking (reads on "an activity"), i.e. exposure to cigarette smoke, may cause a reaction (page 650 paragraph 4).

Claims 5-6, 8, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable
over Berkow in view of Evans as applied to claim 1 above, and further in view of
Rappaport.

As per claim 5, Berkow and Evans do not teach the use of a mouse to select
data.

Rappaport teaches data selection by mouse-clicking (col. 4 lines 39-41, Figure
3B).

At the time the invention was made, it would have been obvious to one of
ordinary skill in the art to include the teachings of Rappaport in the embodiment of
Berkow and Evans with the motivation of selecting and associating data items for
displaying (Rappaport; column 1 line 65-67, column 2 line 34-38) (It is noted that
"chunks" of knowledge are considered data items, according to Rappaport (see all
Figures)).

Claim 6 repeats the limitations of claim 5, and is therefore rejected for the same
reasons, and incorporated herein.

Particularly, the method as taught by Rappaport could be incorporated into the
teachings of Berkow and Evans to provide quick and efficient selection of data items
which represent the reactions.

As per claim 8, Berkow and Evans do not teach displaying of the reaction and the possible influencing agents in a single view.

Rappaport teaches that chunks may be displayed in the same view to facilitate selection (Figures 3A-3B).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Rappaport within the embodiment of Berkow and Evans with the motivation of providing a global view of the knowledge base (Rappaport; col.1 lines 65-67, col. 2 lines 34-38).

Claim 32 repeats the limitations of claims 1 and 4-6, cumulatively, and is therefore rejected for the same reasons, and incorporated herein.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow in view of Evans as applied to claim 1 above, and further in view of Kadtke .

As per claim 9, Berkow and Evans do not teach displaying the graph of the correlation versus time.

Kadtke teaches graphing a correlation parameter versus time delay (Figure 2B).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Kadtke within the embodiment of Berkow and Evans with the motivation of providing efficient data detection (Kadtke;

column 1 line 51-56) and estimating the deterministic properties of observed data

(Kadtke; column 1 line 62-65).

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Berkow in view of Evans as applied to claim 1 above, and further in view of Small.

As per claim 10, Berkow and Evans do not teach "assigning a magnitude value to

the reaction".

Small teaches that magnitude values may be assigned to data points (Figure 2).

At the time the invention was made, it would have been obvious to one of

ordinary skill in the art to include the teachings of Small within the embodiment of

Berkow and Evans with the motivation of providing a method capable of distinguishing

between allergies and infections (Small; column 6 line 10-12).

As per claim 11, this claim is rejected for substantially the same rationale as

applied to the rejection of claim 10, and incorporated herein.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow

in view of Evans as applied to claim 1 above, and further in view of Lowy.

As per claim 13, Berkow teaches that Toxic Shock Syndrome (TSS) is "almost

always associated with menstruation" (page 88 paragraph 5).

Berkow and Evans do not teach that the patient's menstruation cycle is taken into account when diagnosing the allergy.

Lowy teaches that TSS may be caused by an allergic reaction to insect bite (page 527 column 2 paragraph 2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Lowy within the embodiment of Berkow and Evans with the motivation of accurately diagnosing causes of TSS and thereby reducing patient deaths (Lowy; page 527 column 2 paragraph 2).

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow in view of Evans as applied to claim 1 above, and further in view of Mebane.

As per claim 30, Berkow and Evans do not teach that an amount of sleep the patient has may affect a reaction in the patient.

Mebane teaches that the amount of sleep the patient has may be screened as factors that affect patient care (Appendix A, Questions 6 and 25).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Mebane within the embodiment of Berkow and Evans with the motivation of screening patients who improperly seek medical care for behavioral reasons (Mebane, column 1 line 18-21).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow

in view of Evans as applied to claim 1 above, and further in view of Teller.

As per claim 31, Berkow and Evans do not teach downloading Internet

accessible data that relates to environmental exposure and calculating a correlation

between the exposure to patient symptoms.

Teller teaches downloading the pollen count from an Internet database in the

same zip code as the patient and calculating the correlation thereof (page 3 paragraph

0040, page 6 paragraph 0074) (It is noted that pollen count is considered "data that

relates to an environmental exposure").

At the time the invention was made, it would have been obvious to one of

ordinary skill in the art to include the teachings of Teller within the embodiment of

Berkow and Evans with the motivation of providing convenient and minimally intrusive,

as well as dependable monitoring of health signs (Teller; page 1 paragraph 9 and 11).

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow

in view of Evans, Rappaport, Kadtke, and Small.

Claim 33 repeats the limitations of claims 1, 3-6, 9-10, 12, and 14, cumulatively,

and is therefore rejected for the same reasons, and incorporated herein.

(10) Response to Argument

Examiner has forgone responding to the One-Page Summary of Applicant's

Position on page 18 in the brief filed 02/11/2008 in favor of responding to the detailed

arguments provided thereafter.   Appellant makes the following arguments:

A) On page 19, Appellant argues that the applied art do not teach "calculating the

correlation between symptoms and exposure to possible allergens".

B) On page 19, Appellant asserts the advantage of not having to perform a skin

prick test.

C) On page 20, Appellant argues that the applied art do not teach a

computerized way of determining a suspect influencing agent.

D) On page 20, Appellant argues that the applied art do not teach a sorting

scheme as claimed.

E) On page 20, Appellant asserts the advantage of providing a way of readily

identifying the suspect influencing agent.

F) On page 20, Appellant asserts the advantage of adding additional foods and other influencing agents any time after the test begins.

G) On page 20, Appellant argues that the applied art do not teach "entering a plurality of reactions into a computer".

H) On page 20, Appellant argues that the applied art do not teach "a plurality of correlations that includes a correlation that reflects the likelihood that the suspect influencing agent may cause a future reaction".

I) On page 21, Appellant argues that the applied art do not teach "computing a time-delayed correlation".

J) On page 21, Appellant argues that the applied art do not teach assigning a plurality of confidence values to a plurality of correlations.

K) On page 21-22, Appellant argues that the applied art do not teach calculating a plurality of reaction/agent correlations on foods that are intermittently consumed (on and off) over a span of multiple days.

L) On page 22, Appellant asserts the advantage of being capable of picking out an allergen among numerous possible influencing agents based on equally numerous reaction/agent correlations.

M) On page 23, Appellant argues that the applied art do not teach that the actual act of eating can cause a reaction.

N) On page 23, Appellant argues that the applied art do not provide any reason or motivation to combine.

O) On page 24, Appellant argues that the applied art do not teach selecting a reaction via mouse-clicking.

P) On page 24, Appellant argues that the applied art do not teach displaying in a single view of the reaction and the plurality of possible influencing agents.

Q) On page 24, Appellant argues that the applied art do not teach plotting the suspect influencing agent and the reaction versus time.

R) On page 24-25, Appellant argues that the applied art do not teach assigning a magnitude value to the reaction.

S) On page 25, Appellant argues that the applied art do not teach assigning a magnitude value the influencing agent.

T) On page 25, Appellant argues that the applied art do not teach selectively considering or disregarding data collected during a menstrual cycle.

U) On page 25, Appellant argues that the applied art do not teach sleep as a possible influencing agent.

V) On page 26, Appellant argues that claim 31 in its entirety was inadequately addressed by a previous Office Action.

W) On page 26, Appellant argues that Evans does not teach identifying patient allergy.

X) On page 26-27, Appellant asserts that at least some embodiments within the scope of Appellant's claimed invention have advantages over the prior art.

Y) On page 27-28, Appellant argues that the applied art do not teach "computing a plurality of correlations corresponding the plurality of possible influencing agents as each of the plurality of possible influencing agents relate to the reaction".

Z) On page 28-29, Appellant argues that the applied art do not teach comparing a plurality of foods to a single reaction.

Appellant's arguments on page 21 with respect to claim 14-15, page 22-23 with respect to claim 20-28, page 26-27 with respect to claim 1 merely rehash arguments identified above.

Appellant's arguments on page 28, 29-34 merely reiterate verbatim arguments identified above.

Examiner will address Appellant's arguments in sequence as they appear in the brief.

A) On page 7 line 13-15 of the specification Appellant discloses:

The term, "correlation" and derivatives thereof refer to a value or symbol that provides at least some indication of how closely the occurrence of one item relates to the occurrence of another.

According to the definition afforded by Appellant, a "correlation" is defined as a measure of how "closely" one event is related to another event.

Berkow teaches using a skin prick test to identify an allergic reactivity to an allergen (page 650 paragraph 4). Berkow specifically teaches: "clinical significance [of a positive test] is determined when results are correlated with the pattern of symptoms and related to environmental exposures" (page 650 paragraph 4).

Berkow further teaches using an elimination diet to identify a food allergen that may be causing an allergic reaction in the patient (page 328-340). In particular, Berkow teaches determining the relationship of a symptom to food (page 329 paragraph 6). Berkow further teaches removing the food suspected to be the cause of the reaction from the patient's diet and observing the improvement of the symptom (page 329 paragraph 6). Berkow further teaches re-exposing the patient to the food and observing the symptom (page 329 paragraph 6).

According to the teachings of Berkow, the method is capable of identifying possible allergens that may be causing an allergic reaction in a patient. In attempting to isolate and identify an allergen, removing the food makes the symptom goes away, but re-exposing the patient to the food makes the symptom return. Clinical significance may be established for foods that can cause this kind of response in the patient, thereby establishing the food as the cause of the reaction.

Based on the evidence presented above, Examiner submits that Berkow teaches identifying a possible allergen by determining how closely the occurrence of the symptom relates to the exposure of the food. Therefore, Berkow teaches determining a "correlation" between the allergen and the symptom based on the definition afforded by Appellant.

B) Berkow teaches skin prick tests (page 650 paragraph 4) as one way to determine an allergen. Berkow further teaches an elimination diet capable of identifying a food allergen (page 328-330).

Based on the teachings of Berkow, it is clear to one of ordinary skill in the art that the elimination diet does not involve skin prick tests because the patient is fed the food.

Therefore, Examiner submits that Applicant's asserted advantage does not overcome the teachings of the prior art.

C) In response to this argument, Examiner notes that the extent to which a computer and a computer display are used in the method of claim 1 is limited to rudimentary displaying and selecting data. Examiner further notes that neither the limitation "computing a plurality of correlations" or elsewhere in the claim limits the scope of the claim to using a computer to calculate the plurality of correlations. As such, Examiner submits that embodiments comprising manually computing a correlation and entering data into the computer is also enveloped by claim 1.

Berkow teaches a method capable of identifying a food allergy (page 328-330).

Evans teaches a computer-assisted management program capable of displaying and selecting data (Figure 1). Evans further teaches that the computer is capable of providing data processing capabilities, including calculating data (Figure 1), And providing such data to physicians at the time therapeutic decisions are made (page 233 column 2 paragraph 2).

Based on the teachings of Evans, it would be advantageous to provide physicians with computer programs to assist physicians in treating patients.

Based on the evidence presented above, Examiner submits that the applied art suggest Appellant's claimed invention.

D) Appellant provides no definition for "sorting". In determining the scope of the

claim, Examiner relies on Microsoft Computer Dictionary, Fifth Edition, which defines

"sort" as "to organize data [exemplary embodiments of data redacted] in a particular

order".

Berkow teaches determining the relationship between food and symptom in the

patient by exposing the patient to a challenge and observing the patient's response

thereto (page 329 paragraph 6). Berkow further teaches confirming positive challenges

(page 329 paragraph 6).

Based on the teachings of Berkow, Examiner, in applying the broadest and most

reasonable interpretation as is consistent with the specification and the level of ordinary

skill in the art, considers positive challenges to be "sorting" the allergens based on the

positive response in the patient.

Notwithstanding the above, Evans also teaches that the program is capable of

sorting data (page 233 Figure 1).

Based on the evidence presented above, Examiner submits that the applied art

suggest Appellant's claimed invention.

E) As discussed with respect to argument (D) above, Berkow teaches confirming

positive challenges. Examiner submits that the teachings of Berkow are also capable of

readily identifying allergens by separating allergens into groups comprising positive

challenges and negative challenges. Those allergens classified as positive challenges

are readily identified as being suspect for causing the reaction in the patient.

F) Berkow teaches changing the patient's diet on an as-needed basis (page 329

paragraph 8, page 330 Table 20-2). Berkow further teaches adding an additional food

after the test has started (page 329 paragraph 8).

Based on the teachings of Berkow, the patient's diet may be altered at any time

after the test has by the addition of a new food. Therefore, Examiner submits that the

applied art suggests Appellant's claimed invention.

G) Berkow teaches monitoring the recrudescence of symptoms (page 329

paragraph 8).

Based on the teachings of Berkow, patients are monitored for symptoms that

recur.

Additionally, Evans further teaches a computer program capable of storing

patient-specific information viewable in real-time (page 233 column 2 paragraph 1).

Based on the evidence presented above, Examiner submits that monitoring

patient symptoms and storing patient data in a computerized patient record suggest

"entering a plurality of reactions into the computer".

H) Berkow teaches using a skin prick test (page 650 paragraph 4) and

elimination diets (page 328-330) to identify an allergen that can cause a reaction in the

patient. In particular, Berkow teaches using the results of the skin prick test to determine future reactions (page 650 paragraph 4) and the results of the elimination diets to avoid foods that may case a reaction in the future (page 329 paragraph 9).

Berkow further teaches determining the relationship of a symptom to food (page 329 paragraph 6). Berkow further teaches removing the food suspected to be the cause of the reaction from the patient's diet and observing the improvement of symptom (page 329 paragraph 6). Berkow further teaches re-exposing the patient to the food and observing the symptom (page 329 paragraph 6).

Based on the teachings of Berkow, a plurality of foods is analyzed to determine if the food is causing the reaction. Examiner considers the "correlation", as discussed with respect to argument (A) above, analyzed by Berkow to comprise the suspected food as confirmed by the positive challenge. Because the positive challenge is a food that can cause a reaction in the future, and because the patient is advised to avoid this food, Examiner submits that the identified food is considered to represent "a correlation that reflects the likelihood that the suspect influencing agent may cause a future reaction".

To the extent that the skin prick test is limited to a single reaction, Berkow teaches that the skin prick is typically performed by exposing the patient to a plurality of allergens (page 650 paragraph 4, e.g. pollens, molds, pets, etc.). Therefore, it is well known in the art to use multiple skin prick tests to provide multiple challenge-response tests for a plurality of allergens.

I) Berkow discloses that the symptom occurs some time after the food is ingested

(page 329 paragraph 6 and 8). Berkow further teaches determining the possible

allergen, as discussed with respect to argument (A) above and incorporated herein.

Therefore, because the symptom occurs some time after the exposure to the

food, Examiner submits that the applied art suggest "computing a time-delayed

correlation".

J) On page 10 line 8-9 of the specification Appellant discloses:

In some cases, a confidence value 74 may be assigned to a correlation value where

the confidence value provides at least some indication of the correlation value's reliability.

Nonetheless, it is not clear from the phrase "In some cases" if Appellant intends

for this definition to control the scope of the claim.

In determining the scope of claim 17, Examiner relies on Merriam-Webster

Online Dictionary, which defines "confidence interval" as "a group of continuous or

discrete adjacent **_values_** that is used to estimate a statistical parameter (as a mean or

variance) and that tends to include the true value of the parameter a predetermined

proportion of the time if the process of finding the group of values is repeated a number

of times" (emphasis added).

Berkow teaches establishing clinical significance for a positive skin prick test

(page 650 paragraph 4).

Based on the teachings of Berkow, clinical significance is a measure of how reliable the positive result is, and should be correlated with patterns of symptoms and related to environment exposures (page 650 paragraph 4).

Notwithstanding the above, in response to applicant's argument that the applied art do not teach assigning a plurality of confidence values to a plurality of correlations, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Evans teaches using a 95 percent confidence interval (page 235 column 1 paragraph 1).

Based on the teachings of Evans, it is well known in the art of statistics to calculate a confidence interval as a measure of reliability for the statistic in question.

Based on the evidence presented above, Examiner submits that the applied art suggests Appellant's claimed invention.

K) In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., foods that are intermittently consumed (on and off)) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from

the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Assuming *arguendo* that this limitation flows inherently therefrom, Berkow teaches adding a new food to the patient, removing the food, and re-exposing the food within several days (page 329 paragraph 8).

Based on the evidence presented above, Examiner submits that the applied art suggest Appellant's claimed invention.

L) Examiner notes that claims 1 and 19 recite "a plurality". Based on the broadest and most reasonable interpretation, Examiner considers embodiments capable of addressing two or more allergens to be enveloped within the scope of this claim.

While Examiner acknowledges difficulty in manually calculating correlations according to Berkow when the number of possible allergens is large, Examiner submits that the combined teachings of Berkow and Evans alleviates the burden of manual calculations by leveraging the power of computers to efficiently calculate large amounts of data.

Based on the evidence presented above, Examiner submits that Appellant's assertion does not overcome the prior art.

M) Berkow teaches that smoking (reads on "an activity"), i.e. exposure to cigarette smoke, may cause a reaction (page 650 paragraph 4).

Based on the evidence presented above, Examiner submits that the applied art suggests Appellant's claimed invention.

As per Appellant's argument that Berkow does not teach that the actual act of eating can cause a reaction, Examiner submits that it is clear to one of ordinary skill in the art that although a patient may be allergic to a type of food, the patient will not experience a reaction until the food is actually eaten or otherwise ingested. This is taught by Berkow when Berkow suggests patients to avoid eating allergic food (page 329 paragraph 9).

Based on the evidence presented above, Examiner submits that it is clear to one of ordinary skill in the art that it is not the allergic food *per se* that causes the reaction. Instead, it the act of eating the allergic food, i.e. "an activity of the individual", that brings on the allergic reaction.

N) Examiner submits that *KSR International Co. v. Teleflex Inc.*, 550 U.S.--, 82 USPQ2d 1385 (2007) forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See also *Ex parte Smith*, -- USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396). See MPEP 2143.

Nevertheless, Examiner cited specific motivation from the prior art that provides the motivation of selecting and associating data items for display (Rappaport; column 1 line 65-67, column 2 line 34-38).

O) Similar to claim 5, claim 6 recites selecting data by mouse-clicking. The data selected in claim 5 is an influencing agent, whereas the data selected in claim 6 is a reaction.

Nevertheless, the same rationale previously applied in the rejection of claim 5 also applies to claim 6 because it is well known in the art to use a mouse in conjunction with a computer to select data.

P) In response to applicant's argument that the applied art do not teach displaying data in a single view, wherein the data comprises the reaction and the plurality of possible influencing agents, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Examiner notes that Appellant does not argue that any particular limitation *per se* was not known in the prior art. Therefore, Examiner submits that the combined teachings of the applied art suggest Appellant's claimed invention. The motivation to combine would have been providing a global view of the knowledge base (Rappaport; col.1 lines 65-67, col. 2 lines 34-38).

Q) Berkow teaches detecting a possible allergen responsible for causing a symptom in a patient, as discussed with respect to argument (A) above and incorporated herein.

Kadtke teaches a method capable of determining the deterministic property of patterns of data (column 2 line 4-14).

Examiner submits that the teachings of Kadtke are relevant to the teachings of Berkow and Evans in that both Berkow and Kadtke are trying to study the deterministic effect on a system. In Berkow's case, the system is a patient's physiologic system, and the deterministic effect is how the patient would react to a certain allergen.

Kadtke further teaches graphing a correlation parameter versus time delay (Figure 2B).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a 3-dimensional graph comprising the suspect influencing agent, the reaction, and a timescale) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

To the extent that these limitations are claimed, claim 9 recites "plotting a graph of the suspect influencing agent and the reaction versus time" to "help illustrate how well the suspect influencing agent and the reaction correlate".

Based on the teachings of Berkow, a "correlation" is determined between a plurality of allergens and a reaction, as discussed with respect to argument (A) above.

Based on the teachings of Kadtke, the correlation parameter of the system is plotted against a time delay (Figure 2B).

Based on the evidence presented above, Examiner submits that the combined teachings of the applied art suggest Appellant's invention.

R) Applicant provided no definition for "magnitude". In determining the scope of the claim, Examiner relies on Merriam-Webster Online Dictionary, which defines "magnitude" as "a numerical quantitative measure expressed usually as a multiple of a standard unit".

Small teaches a method capable of determining the cause of a reaction in the patient (Abstract), wherein the reaction is assigned a plurality of scores (Figure 1-2).

Based on the definition afforded by Merriam-Webster Online Dictionary, Examiner, in applying the broadest and most reasonable interpretation in light of the specification and the level of ordinary skill in the art, considers assigning a plurality of scores to a reaction to be "a magnitude value".

Based on the evidence presented above, Examiner submits that the combined teachings of the applied art suggest Appellant's claimed invention.

S) Similar rationale as discussed with respect to argument (Q) above is incorporated herein.

In particular, Small teaches a histogram comprising scores assigned to different causes of the reaction, e.g. allergy, URI, sinusitis (Figure 1-2).

Based on the definition afforded by Merriam-Webster Online Dictionary,

Examiner considers assigning a plurality of scores to possible causes of the reaction to

be "a magnitude value".

T) In response to applicant's argument that the references fail to show certain

features of applicant's invention, it is noted that the features upon which applicant relies

(i.e., selectively considering or disregarding data collecting during a menstrual cycle)

are not recited in the rejected claim(s). Although the claims are interpreted in light of

the specification, limitations from the specification are not read into the claims. See *In

re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Insofar as this feature is claimed, claim 13 recites "the first computation and the

second computation are ***differentiated*** from each other by how the first computation

and the second computation ***account for a menstrual period***" (emphasis added).

Examiner submits that nowhere in any claim does Appellant recite considering or

disregarding menstrual data. Appellant only recites two computations, each accounting

for menstrual period data. Examiner further notes that embodiments wherein two

computations accounts for menstrual data in the same manner would also be enveloped

in this claim because Appellant has not claimed that the two computations are actually

different, only that this basis may be used to differentiate the computations.

Berkow teaches that Toxic Shock Syndrome (TSS) is "almost always associated

with menstruation" (page 88 paragraph 5).

Lowy teaches that TSS may be also caused by an allergic reaction to insect bite (page 527 column 2 paragraph 2).

Based on the teachings available in the prior art, a physician diagnosing a patient with TSS would have been motivated to consider insect bite, i.e. non-menstrual related diagnosis, and menstruation, i.e. menstrual-related diagnosis. The motivation to combine would have been to accurately diagnosing TSS and thereby reducing patient deaths (Lowy; page 527 column 2 paragraph 2).

Based on the evidence presented above, Examiner submits that the applied art suggest Appellant's claimed invention.

U) Mebane teaches that the amount of sleep the patient has may be screened as factors that affect patient care (Appendix A, Questions 6 and 25).

Based on the teachings of Mebane, Examiner submits that it is well known in the art that the amount of sleep of a patient can cause reactions in the patient if the amount if minimal or excessive. According to Mebane, this metric is an important part of diagnosing a patient, and should therefore be screened before treating the patient (column 1 line 18-21).

Based on the evidence presented above, Examiner submits that the applied art suggest Appellant's claimed invention.

V) Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without

specifically pointing out how the language of the claims patentably distinguishes them from the references.

Additionally, Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

In particular, Appellant only asserts that the claim in its entirety was inadequately addressed. Examiner has performed a best-effort reading of the arguments, but cannot attribute any reasonable interpretation to Appellant's assertions.

To the extent that Appellant asserts the advantage of helping determine the suspect influencing agent rather than just to explain why an individual's known asthma condition is acting up, Examiner submits that a known allergic condition, e.g. asthma, can be triggered by a plurality of possible causes which are still not known even though it is known that the patient has asthma.

Teller teaches downloading the pollen count from an Internet database in the same zip code as the patient and calculating the correlation thereof (page 3 paragraph 0040, page 6 paragraph 0074) Teller further teaches providing convenient and minimally intrusive, as well as dependable monitoring of health signs (Teller; page 1 paragraph 9 and 11).

Although a patient is known to have asthma, it is not known what may have caused an asthma attack. The teachings of Teller provide a way to determine pollen count in the patient's area, and thereby identifying pollen as a possible cause.

Based on the evidence presented above, Examiner submits that Appellant's asserted advantage do not overcome the prior art.

W) Evans teaches that the system is capable of addressing patient allergies (page 234 Table 1).

X) This argument merely rehashes argument (B) above, and incorporated herein.

In particular, Examiner does not consider the asserted advantages of exemplary embodiments to distinguish the claimed invention over the prior art because other embodiments of the claimed invention were previously known in the art.

Nevertheless, Berkow teaches that an elimination diet may be used, thereby avoiding a skin prick test, as discussed above with respect to argument (B), and incorporated herein.

Y) Berkow teaches at least 4 diets, wherein the patient is placed on each diet for a specific amount of time (page 330 Table 20-2). Berkow further teaches that the patient is observed for symptoms during these periods (page 329 paragraph 6-8).

In making this argument, Appellant's asserts that eliminating five (5) suspect foods may alleviate the symptom, but the actual cause of the symptom is still unknown.

Examiner submits that this characterization of the prior art is inaccurate.

Berkow teaches that a patient is given a diet that alleviates the symptom (page 329 paragraph 8). While symptom-free on the base diet, a new food is then added to the diet (page 329 paragraph 8). For the next period, the patient is exposed to another new food, and this cycle continues until the addition of a food causes the symptom (page 329 paragraph 8). This newly added food is suspect, and is removed for several days and then re-exposed to the patient later (page 329 paragraph 8).

This technique is known as the challenge response protocol, wherein positive challenges cause an observed reaction in the symptom (page 329 paragraph 6). Because many variables can confound the actual cause of the observed symptoms, such as a food being composed of a plurality of different ingredients, Berkow teaches using pure food (page 329 paragraph 7) and exposing the patient to one pure food at a time (page 329 paragraph 8).

Examiner submits that eliminating five foods at a time is an inaccurate characterization of Berkow based on the teachings of Berkow above.

Furthermore, Berkow teaches an embodiment comprising exposing a patient to foods A and B for a first period, and foods A, B, and C for a second period, observing a symptom in the first period or any period thereafter, and determining C as the cause of the reaction. Examiner submits that this embodiment is enveloped within the scope of Appellant's claimed invention.

Z) As discussed with respect to argument (Y) above, Berkow teaches adding one

new food to the patient's diet at a time to determine the single food C responsible for the

single reaction. Since the patient is always exposed to the basic diet of at least two

foods A and B for all periods, Examiner submits that the applied art suggests

determining a single suspect food from a plurality of foods that may be causing a single

reaction.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the

Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Tran N. Nguyen/

Examiner, Art Unit 3626

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